K133868

JUN 04 2014

510(k) Summary – Astral

Date prepared	4 April 2014
Submitter	Peter Jennings Senior Regulatory Affairs Manager
Official contact	Jim Cassi V.P., Quality Assurance Americas ResMed Corp. 9001 Spectrum Center Blvd., San Diego CA 92123 USA Tel: +1 858-836-6081 Fax: +1 858-836-5519
Proprietary name	Astral 100/150
Common name	Continuous ventilator
Classification	21 CFR 868.5895 Primary product code CBK Secondary product code NOU Class II Ventilator, continuous, facility use
Predicate Devices	Respironics Trilogy 200 (K093416) Pulmonetic LTV 1200 (K060647)
Reason for submission	New device

Intended Use

The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 5kg (11 lb) who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

Device Description

The Astral ventilator system uses a micro-processor controlled blower, which, along with valves and pressure and flow sensors, achieves pressure, flow and time regulation of air delivery. Air is directed to the patient via one of three ventilator breathing circuits; double circuit, single circuit with expiratory valve, or single circuit with intentional leak. Supplemental oxygen can be entrained at the inlet to the main turbine. The device provides both therapeutic and technical alarms, and a user interface allowing adjustment of clinical parameters and display of monitored clinical data. The Astral can use external AC or DC power supply and contains an integrated battery.

The Astral is capable of providing the following types of ventilatory support:

- Assist/Control and SIMV with either volume or pressure control
- Continuous Spontaneous Ventilation in either Pressure Support or CPAP
- Volume Assurance and Apnea Ventilation

Substantial Equivalence

The Astral has the following similarities to the previously cleared predicate devices:

- Same intended use
- Same scientific technology
- Similar performance specifications

A comparative summary of the technological characteristics of the Astral device with the primary predicate Trilogy 200 (K093416) is presented below.

Characteristic	Astral (new device)	Trilogy 200 (K093416)	Comparison
Intended Use	Continuous or intermittent ventilatory support Invasive & non-invasive Adult and Pediatric (>5kg) Home, institution/hospital, & portable	Continuous or intermittent ventilatory support Invasive & non-invasive Adult and Pediatric (>5kg) Home, institution/hospital, & portable	Substantially Equivalent *Intended use the same as predicate*
Therapy Modes Supplementary Features	ACV PACV V-SIMV P-SIMV PS & S/T CPAP PAC SV Sigh Apnea Ventilation Manual Breath	CV, AC T & PC SIMV PC-SIMV S, S/T & T CPAP PC AVAPS Sigh Apnea Rate	Substantially Equivalent *Equivalent modes can be configured to deliver the same therapy.* *Apnea Ventilation & Manual Breath substantially equivalent to LTV 1200 (K060647)*
Ventilation Control Parameters	Pressure Range Tidal Volume Respiratory Rate Rise Time Timed Inspiration Sensitivity	Pressure Range Tidal Volume Respiratory Rate Rise Time Timed Inspiration Sensitivity	Substantially Equivalent *Astral provides equivalent range and equivalent or improved accuracy to the predicate device*

Operating Principle	Micro-processor controlled blower as air source	Micro-processor controlled blower as air source	Substantially Equivalent *Same operating principle*
Technology	Software based pressure, flow and time regulation with secondary volume target	Software based pressure, flow and time regulation with secondary volume target	Substantially Equivalent *Same technology*
Circuit Interfaces	Vented & Non-vented Invasive & Non-invasive	Vented & Non-vented Invasive & Non-invasive	Substantially Equivalent
Circuit Types	Double limb Single limb with expiratory valve Single limb with intentional leak	Active Flow Active PAP Passive	Substantially Equivalent *Double limb (Astral) & Active Flow (Trilogy 200) both measure expiratory flow. Double limb also on LTV 1200 (K060647)*
User Interface	LCD screen, hard keys & LED indicators	LCD screen, hard keys & LED indicators	Substantially Equivalent
Power	AC, DC, & Internal battery	AC, DC, & Internal battery	Substantially Equivalent
System Components	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional external humidifier or HME	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional external humidifier or HME	Substantially Equivalent

Non-Clinical Performance Data

Design and Verification activities were performed on the Astral as a result of the risk analysis and product requirements. Testing included accuracy of ventilation volume & pressure controls and monitoring, waveform performance (flow, pressure, volume), accuracy and repeatability of triggering and cycling, endurance and environmental testing, and alarms verification. All tests confirmed the product met the predetermined acceptance criteria. In particular non-clinical side-by-side performance testing was performed for each therapy mode and supplementary feature. Characteristics tested included flow, pressure and volume waveforms, ventilation control parameter accuracy, and patient trigger reliability and synchrony, supporting the claim that the Astral is substantially equivalent to the predicate devices.

The Astral was designed and tested in accordance with the applicable requirements in relevant FDA guidance documents and international standards including:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- ASTM F 1246-91 (2005) Standard Specification for Electrically Powered Home Care Ventilators
- ASTM F 1100-90 (1997) Standard Specification for Ventilators intended for use in Critical Care
- ISO 10651-2:2004. Lung ventilators for medical use - Part 2: Home care ventilators for ventilator-dependent patients
- IEC 60601-1:2005 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: Electromagnetic compatibility - Requirements and tests

Clinical testing was not required.

Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. Performance data supports the claim that the new device is as safe and as effective as the predicate devices. Thus the data in this submission supports the claim of substantial equivalence to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2014

ResMed Corporation
Mr. Jim Cassi
V.P. of Quality Assurance Americas
9001 Spectrum Center Blvd.
San Diego, CA 92123

Re: K133868
Trade/Device Name: Astral 100/150
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, continuous, facility use
Regulatory Class: II
Product Code: CBK, NOU
Dated: April 4, 2014
Received: April 7, 2014

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
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Enclosure

K133868

Indications for Use

510(k) Number (if known):

Device Name: Astral 100/150

Indications for Use:

The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 5kg (11 lb) who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

Prescription Use ____X_____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of Device Evaluation (ODE)

FDA Anya C. Harry -S
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